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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,844	12/15/2004	Amnon Sintov	030231-0155	9004

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FOLEY AND LARDNER LLP
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EXAMINER	
AHMED, HASAN SYED	
ART UNIT	PAPER NUMBER
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,844	SINTOV ET AL.	
	Examiner	Art Unit	
	Hasan S. Ahmed	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

- Receipt is acknowledged of applicants' amendment/remarks, which were filed on 29 November 2006.
- The amendment filed on 29 November 2006 has been entered.
- The claim objections and 35 USC 112 rejection of record (Office action mail date 29 August 2006) are withdrawn in light of the amendment.
- Claims 1-12 remain rejected under 35 USC 102, 103, and provisional obviousness-type double patenting

* * * * *

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-3, 6-8, 11 and 12 remain rejected under 35 U.S.C. 102(a) as being anticipated by Luo, *et. al.* (U.S. Patent Application No. 2001/0051166).

Luo, *et. al.* disclose a transdermal or topical delivery system (*see* paragraph 0019). The disclosed transdermal or topical delivery system is the instant transdermal or topical delivery system as claimed:

- the transdermal delivery of local anesthetics of instant claim 1 (*see* paragraph 0069);
- the transdermal delivery of immunosuppressive agents of instant claim 1 (*see* paragraph 0063);

- the transdermal delivery of neurologically effective drugs of instant claim 1 (*see* paragraph 0063);
- the transdermal delivery of polypeptide (peptide) drugs of instant claim 1 (*see* paragraph 0063);
- the water-miscible tetraglycol of instant claim 1 (*see* Table 10);
- the hydrogel form of instant claim 1 (*see* pargraph 0153);
- the microemulsion (emulsion) of instant claim 1 (*see* paragraph 0136);
- the ionized polymer of instant claim 2 (*see* paragraph 0138);
- the acrylic polymer of instant claim 3 (*see* paragraph 0138);
- the granisetron of instant claim 6 (*see* paragraph 0070);
- the hydrogel patch of instant claim 7 (*see* paragraph 0153);
- the skin penetration (permeation) enhancer of instant claim 8 (*see* paragraph 0019);
- the transdermal hydrogel comprising an alcohol-miscible drug combined with water-miscible tetraglycol and water of instant claim 11 (see paragraphs 0069, 0153 and Table 10);
- the topical delivery of local anesthetics of instant claim 12 (*see* paragraph 0002);
- the topical delivery of immunosuppressive agents of instant claim 12 (*see* paragraph 0063);
- the topical delivery of neurologically effective drugs of instant claim 12 (*see* paragraph 0063);

- the topical delivery of polypeptide (peptide) drugs of instant claim 12 (*see* paragraph 0063);
- the water-miscible tetraglycol of instant claim 12 (*see* Table 10);
- the hydrogel form of instant claim 12 (*see* pargraph 0153);
- the microemulsion (emulsion) of instant claim 12 (*see* paragraph 0136);

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 4 and 5 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Luo, *et. al* in view of Sintov, *et. al.* (WO 02 09763).

Luo, *et. al.* teach a transdermal or topical delivery system (*see* above).

Luo, *et. al.* explain that combining the disclosed agents into one transdermal/topical delivery system is beneficial because it leads to an enhanced "rate at which an active agent administered to a patient's body surface permeates into and/or through the body surface." *See* paragraph 0008.

The disclosed delivery system differs from the instant claims in that it does not disclose the guar-based polymer (instant claim 4) hydroxypropyl guar hydroxypropyltrimonium chloride (instant claim 5).

Sintov, *et. al.* teach a transdermal delivery system (*see* page 6) in hydrogel form (*see* page 7).

The disclosed hydrogel may comprise guar-based polymer hydroxypropyl guar hydroxypropyltrimonium chloride (see page 6).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make a hydrogel based transdermal drug delivery system using the guar-based polymer hydroxypropyl guar hydroxypropyltrimonium chloride as taught by Luo, *et. al.* in view of Sintov, *et. al.* One of ordinary skill in the art at the time the invention was made would have been motivated to make such a drug delivery system to enhance transdermal drug delivery rates, as explained by Luo, *et. al.*

*

2. Claims 9 and 10 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Luo, *et. al* in view of Sintov, *et. al.* (WO 02 09763).

Luo, *et. al.* teach a transdermal or topical delivery system (*see* above).

Luo, *et. al.* explain that combining the disclosed agents into one transdermal/topical delivery system is beneficial because it leads to an enhanced "rate at which an active agent administered to a patient's body surface permeates into and/or through the body surface." *See* paragraph 0008.

The disclosed delivery system differs from the instant claims in that it does not disclose a non-ionic surfactant (instant claim 9), such as sorbitan sesquioleate (instant claim 10), as a penetration enhancer.

Sintov, *et. al.* teach a transdermal delivery system (*see* page 6) in hydrogel form (*see* page 7).

The disclosed hydrogel may comprise a non-ionic surfactant, such as sorbitan sesquioleate, as a penetration enhancer (see page 7).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make a hydrogel based transdermal drug delivery system using a non-ionic surfactant, such as sorbitan sesquioleate, as a penetration enhancer as taught by Luo, *et. al.* in view of Sintov, *et. al.* One of ordinary skill in the art at the time the invention was made would have been motivated to make such a drug delivery system to enhance transdermal drug delivery rates, as explained by Luo, *et. al.*

* * * * *

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-12 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of copending Application No. 10/343,008 ('008). Although the conflicting claims are not identical, they are not patentably distinct from each other because '008 teaches a transdermal delivery system in hydrogel form using water-miscible tetraglycol and water to dissolve drug (*see* claim 1).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

* * * * *

Response to Arguments

Applicants' arguments filed 29 November 2006 have been fully considered but they are not persuasive.

Applicants argue that the Luo reference does not anticipate the instant claims because, "...Luo does not describe microemulsions and their formation according to the present invention." *See* remarks, page 5, last paragraph.

Examiner respectfully submits that the Luo reference anticipates the instant application when the term "microemulsions" is given its broadest reasonable interpretation.

Examiner appreciates the Danielson and Lindman definition of "microemulsion" provided on page 5 of the remarks after the first Office action (filed on 29 November

2006). However, a careful review of the original disclosure of the instant application does not reveal any definition of the term "microemulsion." Applicants provide no guidance as to their intended interpretation of this term. Applicants do not recite the diameter of the "microemulsions" they disclose, nor do they describe how the "microemulsions" are formed, adding further ambiguity to the form of emulsion they are actually claiming.

The Danielson and Lindman definition of "microemulsion" cited by applicants in the remarks after the first Office action (filed on 29 November 2006) is one of many in the art. Furthermore, the relationship between a microemulsion and an emulsion is disputed in the art. As Attwood explains, "[s]ince the term "microemulsion" was first introduced...there has been much dispute about the relationship of these systems to micellar solubilized systems and to emulsions." *See* David Attwood, *Microemulsions*, *in* Colloidal Drug Delivery Systems 2, 31 (Jörg Kreuter ed., 1994).

As applicants have not provided their own definition of "microemulsion", examiner has given the term its broadest reasonable interpretation, i.e. that it is a type of emulsion. As such, examiner respectfully submits that the Luo reference anticipates the instant application as disclosed.

* * * * *

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hasan S. Ahmed whose telephone number is 571-272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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TC 1600